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Certified by



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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

17264 U.S. PTO
08/20/03



16235 U.S. PTO
60/497025
08/20/03



Express Mail Label No. EV349882539US

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 Additional inventors are being named on the 1 separately numbered sheets attached hereto**TITLE OF THE INVENTION (500 characters max)**

BLOOD SAMPLING DEVICE

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ENCLOSED APPLICATION PARTS (check all that apply)

Specification Number of Pages CD(s), Number

Drawing(s) Number of Sheets Other (specify)

Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

Applicant claims small entity status. See 37 CFR 1.27.

A check or money order is enclosed to cover the filing fees

The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: FILING FEE AMOUNT (\$)

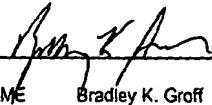
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

 No. Yes, the name of the U.S. Government agency and the Government contract number are: _____.

[Page 1 of 2]

Respectfully submitted,

SIGNATURE 

TYPED or PRINTED NAME

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Date

8/20/2003

REGISTRATION NO.

39,695

(if appropriate)

Docket Number:

2G02.1-081

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PROVISIONAL APPLICATION COVER SHEET*Additional Page*

PTO/SB/16 (05-03)

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Docket Number 2G02.1-081

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[Page 2 of 2]

Number 1 of 1**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

PATENT
ATTORNEY DOCKET NO: 2G02.1-081

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PROVISIONAL

APPLICATION FOR LETTERS PATENT

UNITED STATES OF AMERICA

Be it known that **Richard W. LEVAUGHN** of 532 Sullivan Road, Newnan, Georgia 30265, USA; **Gwenn E. KENNEDY** of 5 North Lakeside Drive, Ellenwood, Georgia 30294, USA; **Stephen FLYNN** of 605 Wheatleigh Curve, Peachtree City, Georgia 30269, USA; **Carl E. GRIFFIN** of 2081 Breconridge Drive, Marietta, Georgia 30064, USA; **John C. IRWIN** of 148 Springwater Trace, Woodstock, Georgia 30188, USA; **Mary Kate PYNES** of 1175 Old Harris Road #312, Dallas, Georgia 30157, USA; **Stephanie J. CAMPBELL** of 1114 Hazeltine Lane, Kennesaw, Georgia 30152, USA; **Christopher J. RUF** of 2120 Ithica Drive, Marietta, Georgia 30067-7054, USA; **Mitchell A. SOLIS** of 1975 Lexington Lane, Cumming, Georgia 30004, USA; **Avi M. ROBBINS** of 539 Timber Ridge Drive, Longwood, Florida 32779, USA; and **Jason R. HEATH** of 1530 Mcadoo Drive SW, Marietta, Georgia 30064, USA, have invented new and useful improvements in a

BLOOD SAMPLING DEVICE

for which the following is a specification.

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BLOOD SAMPLING DEVICE

Cross-Reference to Related Applications

[0001] This application is a continuation-in-part of International Application No. PCT/US03/05159, designating the U.S., filed February 20, 2003; which claims the benefit of U.S. Provisional Patent Application Serial No. 60/387,639, filed June 11, 2002, and of U.S. Provisional Patent Application Serial No. 60/411,834, filed September 17, 2002; and which claims priority to German Patent Application, Serial No. DE 10208575.7, filed 21 February 2002, German Patent Application, Serial No. DE 10245721.2, filed 24 September 2002, and German Utility Model No. DE 20213607.8, filed 21 February 2002; the content of all of which are hereby incorporated herein by reference in their entireties.

Technical Field

[0002] The present invention relates generally to medical devices and procedures, and more particularly to lancing devices for the collection and/or analysis of samples of blood or other bodily fluid.

Background of the Invention

[0003] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of an animal or human subject. For example, a sharp lancet tip is commonly used to puncture the subject's skin at a lancing site to obtain a sample of blood, interstitial fluid or other body fluid, as for example in blood glucose monitoring by diabetics and in blood typing and screening applications.

[0004] In some instances, a person must periodically sample their blood for multiple testing throughout the day or week. Because re-use of a lancet can result in infection or spread of bloodborne contaminants, persons requiring repeated testing often must carry multiple lancets with them. This can be inconvenient and lead to

reduced compliance with a prescribed test regimen. If the person is also required to carry separate sample collection strips or test media and also a monitor for sample analysis, the inconvenience is worsened, potentially reducing compliance further.

[0005] Accordingly, it can be seen that needs exist for a convenient, compact 5 multi-use lancing device. Needs also exist for a compact sampling device that includes lancets, test media and a sample analysis device in a combined apparatus. It is to the provision of an improved sampling device meeting these and other needs that the present invention is primarily directed.

Summary of the Invention

10 [0006] Briefly described, example embodiments of the present invention include an improved sampling device that is convenient, compact, and includes multiple lancets in a single cassette or cartridge. Further example embodiments of the present invention include a compact sampling device that includes lancets, test media and a sample analysis device in a combined apparatus. The present invention preferably 15 increases convenience for the user, thereby encouraging more frequent testing and insuring compliance with the subject's prescribed testing regimen.

[0007] In one aspect, the invention is a lancing device including a plurality of lancets. Each lancet has a separate drive spring independently associated therewith to propel the lancet along a lancing stroke from a retracted position to an extended 20 position.

[0008] In another aspect, the invention is a lancing device having at least one lancet with a detachable endcap, and a lancet retainer independently associated with each lancet. The lancet retainer is movable between a first position and a second position, and movement of the lancet retainer between the first position and 25 the second position removes the detachable endcap from the lancet and retracts the lancet into a cocked position.

[0009] In still another aspect, the present invention is a lancing device including a plurality of lancets, wherein the lancets can be fired in any order.

[0010] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, 5 and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

10 **Brief Description of the Drawings**

[0011] FIGURE 1 is a perspective view of an assembled sampling device according to an example embodiment of the present invention.

[0012] FIGURE 2 is an exploded view of the sampling device of Fig. 1, showing meter, detector, and lancing cartridge components of the apparatus separated from 15 one another.

[0013] FIGURE 3 is a perspective view of a lancing cartridge portion of the sampling device of Fig. 1, with a cover portion removed to show inner components, according to an example embodiment of the present invention.

[0014] FIGURE 4 is an exploded view of a lancing cartridge of the sampling 20 device of Fig. 1, according to an example embodiment of the present invention.

[0015] FIGURE 5A is a side view of the assembled lancing cartridge of the sampling device of Fig. 1, according to an example embodiment of the present invention.

[0016] FIGURE 5B is a cross sectional top view of the lancing cartridge taken 25 along axis A—A of Fig. 5A.

[0017] FIGURE 6 is another perspective view of a lancing cartridge according to an example embodiment of the present invention, with the cover portion removed.

[0018] FIGURE 7 is a perspective view of the inner face of a cover portion of a lancing cartridge according to an example embodiment of the present invention.

5 [0019] FIGURE 8 is a perspective view of a meter portion of a sampling device according to an example embodiment of the present invention.

Detailed Description of Example Embodiments

[0020] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the 10 accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification 15 including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another 20 embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[0021] With reference now to the drawing figures, a blood sampling device 10 is shown by way of example embodiments of the present invention. As seen in Figures 1 25 and 2, in one embodiment of the invention, the blood sampling device 10 comprises an apparatus combining a lancing cartridge component 12 containing one or more lancets for piercing the skin to generate a sample of blood or other body fluid, a detector

component 14 containing test strips or other media for sample collection and/or processing, and a meter component 16 for analyzing a constituent analyte of a collected sample. In alternate embodiments, the invention comprises any one of these components separately, or any two or more components in combination.

5 The Lancing Apparatus

[0022] The lancing cartridge 12 of the present invention preferably comprises a base or lancet disc 18 that optionally can be rotationally coupled to one or more other components such as meter 16 and/or detector 14 in a combination apparatus, or can separately comprise a standalone multi-use lancing device. As seen best in Figure 3, 10 in an example embodiment, the base 18 is a generally circular disk having a circular central opening, and preferably includes a plurality of pairs of radially extending lancet tracks 20 having lancets 22 slidably disposed therebetween. Each lancet 22 preferably comprises a body 24, having a needle or blade (not shown) mounted therein with a sharp tip projecting from one end of the body and covered with an end cap 28 to 15 protect against accidental contact or needle-sticks. The lancet body 24 preferably further defines at least one recess 30 for engagement with a triggering mechanism 32. In the example embodiments, a spring 34 is provided to drive the lancet from a retracted position wherein the sharp tip is shielded within the cartridge and an extended position wherein the sharp tip extends a distance outwardly of the cartridge. 20 The spring 34 optionally also serves to retract the lancet tip back within the cartridge after firing, or alternatively a separate return spring is provided. In further alternate embodiments, a cam, motor or other drive means propels the lancet from its retracted position to its extended position. In example embodiments, each lancet 22 is 25 associated with its own spring 34, such that each lancet has its own independent drive mechanism. In this manner, the lancets can be delivered to the end user in an initially "cocked" configuration, with each drive spring compressed and ready for firing, thereby improving user convenience by eliminating the need to cock the device before each

lancing operation. In alternative embodiments, the device is delivered with the springs relaxed and each lancet 22 is initially stored in an "uncocked" position such that the device is cocked by the user before lancing.

[0023] Each lancet 22 is preferably translationally mounted between a pair of 5 lancet tracks 20, which define a path of travel between the retracted and extended positions. A lancet retainer 42 retains each lancet 22 in a first position along the path of travel until the lancet is intended to be made ready for firing to lance the skin at a sampling site. As noted above, the first position may be a cocked position or an uncocked position. As seen in the example embodiment of Figures 4, 5 and 6, the 10 lancet retainers 42 each comprise an outer flange that covers a respective one of a plurality of openings 44 through the rim of a top plate or cover 46. Each lancet retainer 42 also includes an inner arm 50 that projects through a respective one of a plurality of slotted openings 52 through the cover 46 and into engagement with a cooperating 15 recess 53 of a respective lancet 22 to prevent firing of that lancet upon activation of a triggering mechanism 32 unless that lancet has been made ready for firing. Each lancet retainer 42 preferably further comprises a resilient tab 48 projecting from its outer flange with a projection 49 thereon that alternatively engages a first recess 40 formed in the outer rim of the base 10 to secure the lancet retainer in a first position covering its respective opening 44, or a second recess 41 formed in the outer rim of 20 the base to secure the lancet retainer in a second position exposing its respective opening 44.

[0024] A specified lancet 22 is made ready for firing by moving the lancet 25 retainer 42 associated with that lancet from its first position to its second position. This simultaneously exposes the opening 44 in the housing through which the sharp tip of the lancet projects in its extended position, and moves the inner arm 50 out of engagement with the cooperating recess 53 of the lancet to free the lancet to slide along the path of travel of the lancing stroke. The arm 50 preferably comprises an inclined face forming a wedge 54 that separates the protective endcap 28 from the

lancet being made ready for firing. As the lancet retainer 42 is moved from its first position to its second position, the wedge 54 is driven through the recess 53, causing detachment of the endcap 28 from the rest of the lancet 22. The detached end cap is preferably then deposited into a recess 55 out of the way of the lancet's path of firing.

- 5 The lancet cap may be moved into the recess 55 by a spring member, gravity, magnetic attraction, or other biasing means, and optionally is replaced onto the lancet tip after firing. For example, in one embodiment of the invention, the endcap 28 comprises a magnetic material and a magnet is disposed in the housing adjacent the recess 55 to move the detached endcap into the recess. One or more fins or other
- 10 guide members are optionally formed in the housing to guide the detached endcap 28 into the recess 55. If the lancets 22 are not initially provided in a cocked position, movement of the lancet retainer 42 from its first position to its second position can also serve to cock the lancet. As the wedge 54 moves across a cooperating surface of the lancet, the inclined face of the wedge acts as a cam to drive the lancet radially inwardly
- 15 in the direction of the lancet's retracted position.

[0025] Because each lancet 22 includes its own associated drive means, independent of the other lancets, and because each lancet retainer 42 is operable independent of the other lancet retainers, the lancets 22 can be used in any order as determined by the user. After firing a lancet, the associated lancet retainer 42 is preferably returned to its first position to cover the opening 44 to prevent accidental contact with a contaminated lancet tip and to prevent foreign debris from entering the device.

[0026] The lancing apparatus of the present invention preferably further comprises a triggering mechanism for releasing one or more lancets 22 that have been made ready for firing as described above. Upon releasing the triggering mechanism, the lancet 22 is driven from its cocked or retracted position, along the path of travel of the lancing stroke under the influence of the drive means, into the extended position

for lancing the skin of a subject placed against or adjacent the opening 44. The triggering mechanism preferably comprises a trigger button 32 having one or more cantilevered resilient fingers 60 extending therefrom for engaging each lancet 22. With reference to Figs. 3, 4 and 6, in the depicted embodiment, a plurality of pairs of fingers 60 are provided, each pair engaging a respective one of the lancets 22. Each of the fingers 60 preferably comprises a barb 62 at its free end, for releasable engagement with a cooperating recess 30 in the side of the body 24 of the associated lancet 22. Slots or openings 64 are preferably provided through the top cover plate 46 for passage of the fingers 60.

10 [0027] Prior to releasing the triggering mechanism to fire a lancet 22, the barbs 62 engage the recesses 30 to hold the lancet in the retracted or cocked position. When the triggering mechanism is released, interaction of an inclined face of the barb 62 with a cooperating surface of the lancet tracks 20 spreads the pair of fingers 60 apart and out of engagement with the recesses 30, releasing any lancet 22 that has 15 been made ready for firing as described above. Lancets that have not been made ready for firing remain constrained in their retracted positions by their associated lancet retainers 42, and are not fired upon releasing the triggering mechanism. In example embodiments, two or more lancets can be made ready for firing, and can be fired simultaneously to lance the skin at multiple lancing sites, so that multiple samples can 20 be separately analyzed or a larger volume of body fluid collected. This can help reduce discomfort or anxiety that might otherwise result if multiple lancing operations were performed sequentially rather than simultaneously. Alternatively, interlocks can be provided to prevent more than one lancet from being fired at once. The device optionally comprises means for preventing re-use of a lancet after it has been fired, 25 such as a one-way latching mechanism or a locking element that blocks the lancet path to prevent re-cocking or re-firing.

[0028] Figure 7 shows the inside of the top plate or cover 46 of the lancing device according to an embodiment of the invention. One or more posts 66 preferably

project from the cover 46 for attachment of an inner end of the drive spring 34. In the depicted embodiment, a plurality of pairs of posts 66 are provided, each pair configured to hold a drive spring 34 captive therebetween. The outer end of the spring is preferably securely attached to the lancet 22, for example by capture between two 5 posts 26 projecting from the lancet body. By attaching the inner end of the spring 34 to the housing 46 and the outer end of the spring to the lancet 22, the spring can function both as a drive spring to propel the lancet from the retracted position to the extended position upon firing, and as a return spring to retract the lancet back into the housing after lancing. One or more recesses or other surface features 86 are preferably 10 formed in the inner hub surface of the central opening in the cover 46 for engagement with a cooperating element of the detector 14 and/or meter 16, as described further below.

The Detector

[0029] As seen in Figs. 1 and 2, an example embodiment of the detector 15 component 14 of the sampling device comprises a generally circular disk having a circular central opening. The detector 14 is preferably shaped to generally match the profile of the lancing device component 12 and the meter 16, and is configured for detachable and rotatable coupling with the lancing apparatus 12 and the meter 16. The detector 14 preferably comprises a plurality of test strips, assay material or other 20 test media for collecting and/or processing a sample of blood or other body fluid to detect and/or quantify a specified analyte such as blood glucose, cholesterol, blood cell counts, gases such as oxygen and carbon dioxide, or salts such as potassium and sodium. The detector 14 may further comprise a chemical detection system, such as for example, an enzyme linked immunosorbant assay (ELISA), an optic detection 25 system, or combinations thereof, such as for example, the use of immunofluorescence (IFA).

[0030] The detector 14 can comprise the same or a different number of test media elements as the lancing apparatus 12 has lancets. In example embodiments, the detector 14 is independently rotatable from the lancing apparatus 12 and the meter 16. In alternate embodiments, the detector's 14 rotation is indexed to the rotation of the base disc 18 of the lancing apparatus. The detector 14 preferably has one or more recesses or other surface features 70 formed in an inner hub surface of its central opening for interaction with cooperating elements of the lancing apparatus 12 and/or the meter 16. One or more indentations, ridges, or other surface features 72 are preferably located along the outer rim of the detector 14 for alignment and indexing of the test media with the meter 16.

The Meter

[0031] As seen best in Figs. 1, 2 and 8, an example embodiment of the meter 16 preferably comprises a body portion having one or more legs 80 projecting therefrom for engaging the lancing apparatus 12 and/or the detector 14. Shoulders 84 are preferably provided on the legs 80 for providing a snap-fit connection with the lancing apparatus 12 and/or the detector 14, to retain the apparatus in an assembled configuration. One or more protrusions or other surface features 82 on the legs interact with the recesses 70, 86 of the detector 14 and/or the lancing apparatus 12 for alignment and indexing of relative rotation between the components, to provide an audible click or tactile indexing as the detector and/or the lancing apparatus are rotationally advanced. Alternatively or additionally, one or more ridges or other surface features 88 are preferably provided on an inner rim surface of the meter 16 for interaction with the indentations 72 or other surface features of the detector 14 to provide indexed rotation and alignment between these components. The meter 16 preferably comprises electronic processing means of standard known varieties for analyzing and/or displaying sample test results.

[0032] The device is assembled for use by snapping the detector 14 in place with the legs 80 of the meter 16 extending through the central opening of the detector

and the proximal shoulders 84 snap-fit over the detector. The lancing apparatus 12 is then installed over the detector with the legs 80 extending through its central opening and the distal shoulders 84 snap-fit over the lancing apparatus. The lancing apparatus 12 and the detector 14 are preferably symmetric, so that no alignment of these 5 components with the meter is required upon assembly. And because the lancets 22 can be fired independently and in any order, it is not necessary to load the lancet cartridge of the present invention in any specified orientation. One or more of the lancet retainers 42 of the lancing apparatus 12 are moved circumferentially along the rim of the lancing apparatus, from the first position to the second position, to expose 10 an associated opening 44 and to make an associated lancet ready for firing as described in greater detail above. The user then places the skin of a desired sampling site against or adjacent the exposed opening 44. The device is triggered by pressing trigger button 32, and the sharp tip of the lancet is driven through its lancing stroke, from the retracted position to the extended position where it pierces the skin of the 15 sampling site. A sample of blood is expressed from the wound at the sampling site and transferred to test media of the detector 14. The sample is processed and information regarding an analyte is displayed on the meter 16. After lancing, the lancet retainer 42 is returned to cover the opening 44, and the device is ready for subsequent use. One or both of the lancing apparatus 12 and/or the detector 14 can be removed, disposed 20 of, and replaced onto the reusable meter 16 when fully used. Optionally, interchangeable replacement lancet cartridges can be provided with lancets having tips of different standard lengths, whereby a user can select a desired depth of penetration by appropriate selection of the lancet cartridge to be installed.

[0033] While the invention has been described with reference to preferred and 25 example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

CLAIMS

What is claimed is:

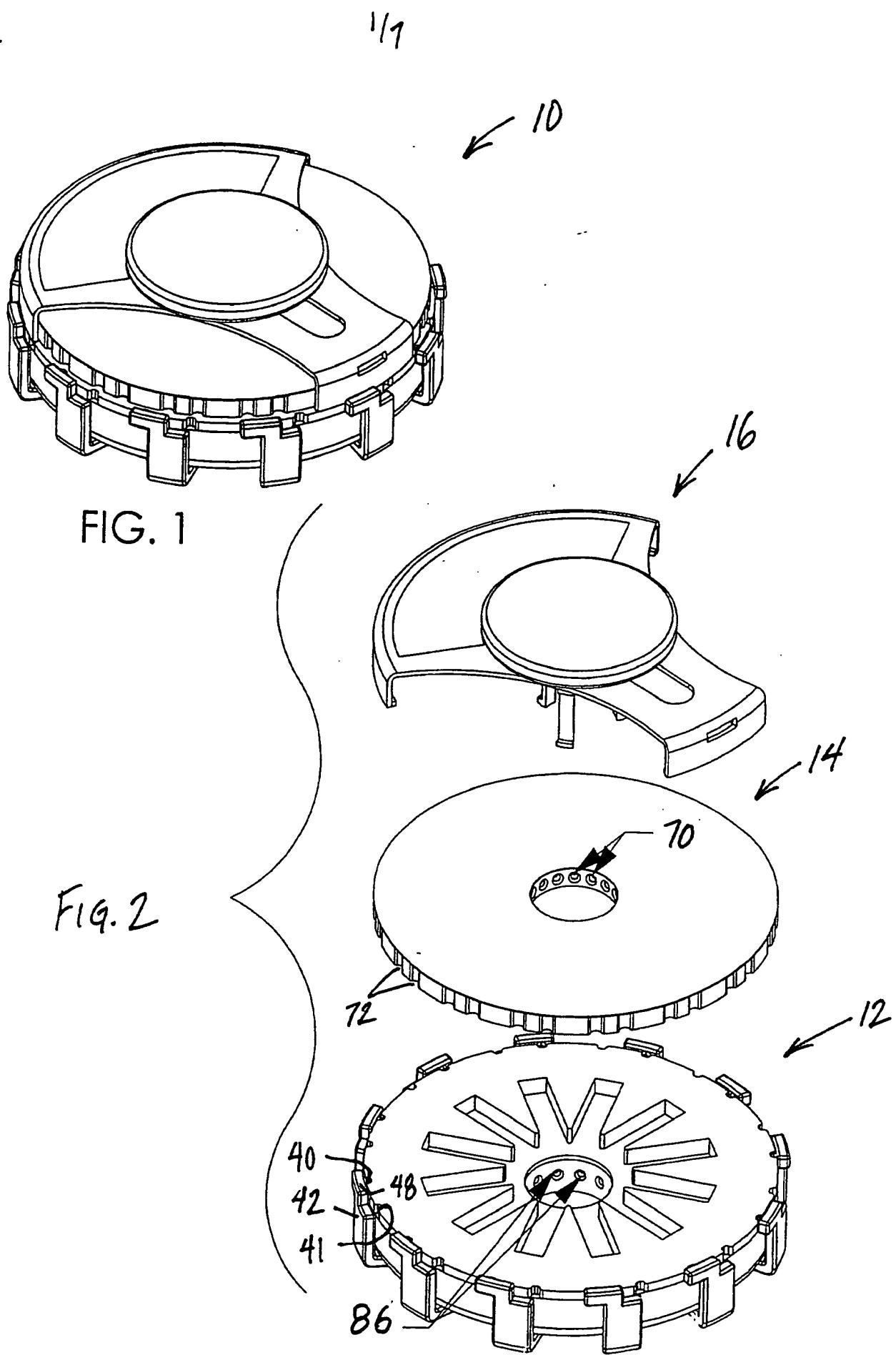
1. A lancing device comprising a plurality of lancets, wherein each lancet has a separate drive spring independently associated therewith to propel the lancet along a lancing stroke from a retracted position to an extended position.
2. The lancing device of Claim 1, further comprising a lancet retainer associated with each lancet, the lancet retainer movable between a first position in engagement with the lancet for holding the lancet in the retracted position, and a second position out of engagement with the lancet.
3. The lancing device of Claim 2, further comprising a housing defining a plurality of openings, each opening associated with a respective one of said plurality of lancets, and wherein each said lancet retainer covers a respective one of said plurality of openings when the lancet retainer is in its first position.
4. The lancing device of Claim 2, wherein each said lancet retainer comprises an arm having an inclined face for engagement with a cooperating surface of the associated lancet as the lancet retainer moves from its first position to its second position.
5. The lancing device of Claim 4, wherein the inclined face interacts with a cooperating portion of an endcap of the lancet to detach said endcap from the lancet.
6. The lancing device of Claim 4, wherein the inclined face interacts with the lancet to move the lancet into a cocked position.
7. The lancing device of Claim 1, wherein the plurality of lancets are arranged generally radially in a plane, and wherein each lancet comprises a detachable endcap that is moved out of said plane upon detachment.

8. The lancing device of Claim 1, further comprising a base having a plurality of pairs of lancet tracks, each pair of lancet tracks defining a path of travel of the lancing stroke for an associated one of the plurality of lancets.
9. The lancing device of Claim 1, further comprising a trigger button having a plurality of resilient fingers extending therefrom, each of said fingers releasably engaging one of said plurality of lancets.
10. The lancing device of Claim 9, wherein actuation of said trigger button simultaneously releases each of said fingers from its associated lancet.
11. A sampling device comprising the lancing device of Claim 1, releasably coupled to a detector component comprising test media, and to a meter for analyzing a collected sample of body fluid.
12. A lancing device comprising:
 - at least one lancet having a detachable endcap; and
 - a lancet retainer independently associated with each said at least one lancet, the lancet retainer movable between a first position and a second position,
 - wherein movement of the lancet retainer between the first position and the second position removes the detachable endcap from the lancet and retracts the lancet into a cocked position.
13. The lancing device of Claim 12, further comprising a housing defining an opening associated with each said at least one lancet, and wherein the lancet retainer associated with said lancet covers the opening in the first position and exposes the opening in the second position.
14. The lancing device of Claim 12, further comprising a separate drive mechanism for each lancet.

15. The lancing device of Claim 12, wherein the lancet retainer comprises a wedge, and wherein upon movement of the lancet retainer between the first position and the second position, said wedge drives the detachable endcap in an outward direction and drives the lancet in an inward direction.
16. The lancing device of Claim 12, comprising a plurality of lancets and a trigger capable of simultaneously releasing more than one lancet.
17. A lancing device comprising a plurality of lancets, wherein the lancets can be fired in any order.
18. The lancing device of Claim 17, wherein each lancet comprises a separate and independently operable drive mechanism.
19. The lancing device of Claim 18, wherein lancet is delivered to the user with the drive mechanism of each lancet cocked for firing.
20. The lancing device of Claim 19, further comprising a plurality of lancet retainers, each lancet retainer associated with one of said plurality of lancets and movable between a first position in engagement with the associated lancet and a second position out of engagement with the associated lancet.

ABSTRACT

A sampling device having a lancing apparatus, a detector, and a meter. The lancing apparatus includes a replaceable cartridge of lancets, each lancet having an independent arming and drive mechanism enabling non-sequential and/or simultaneous firing of lancets.



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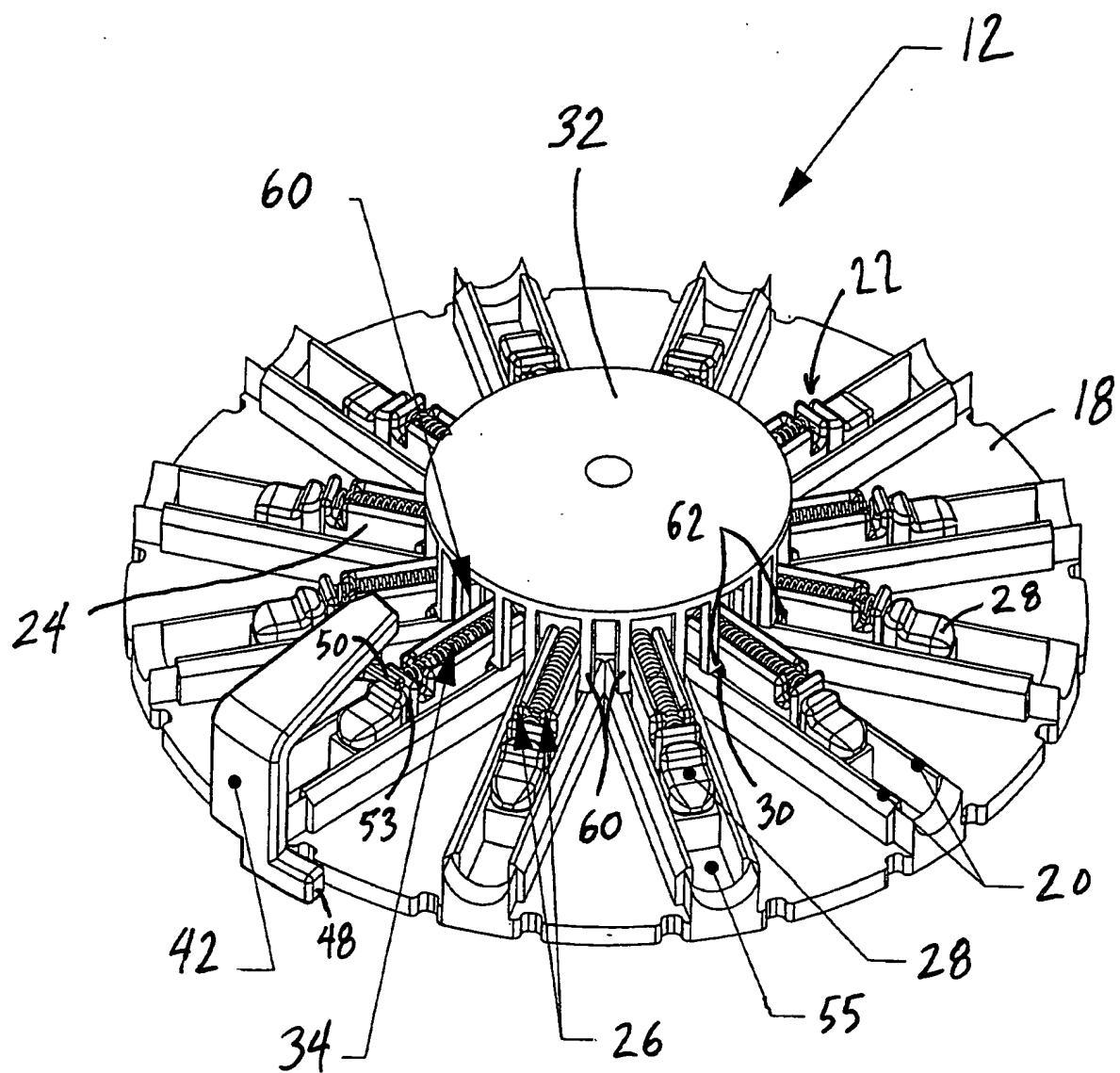


FIG. 3

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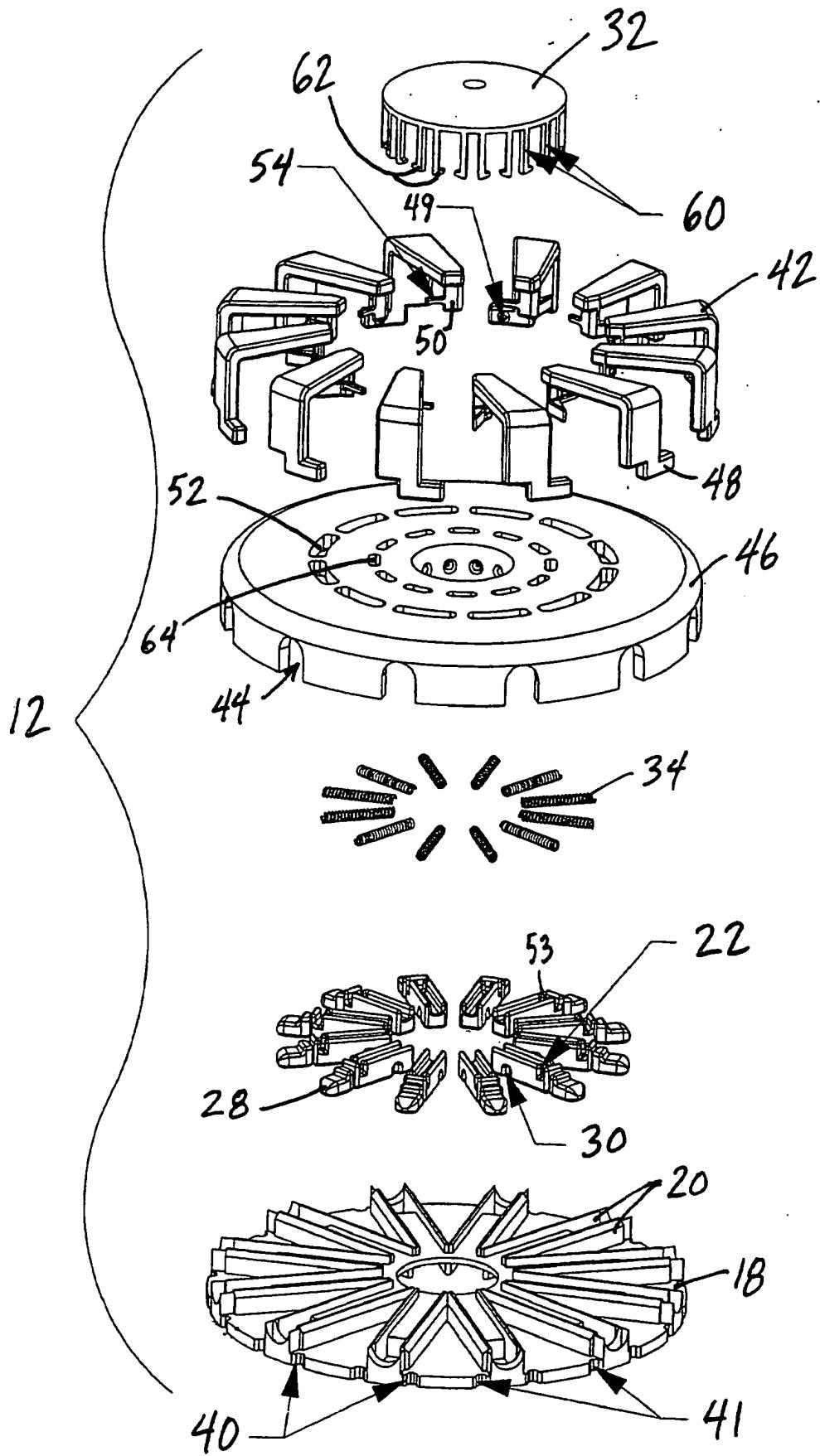


FIG. 4

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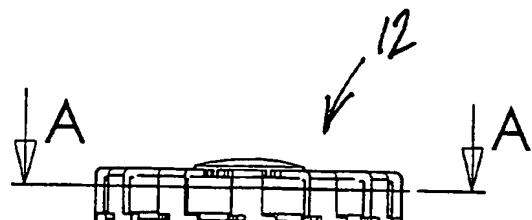


FIG. 5a

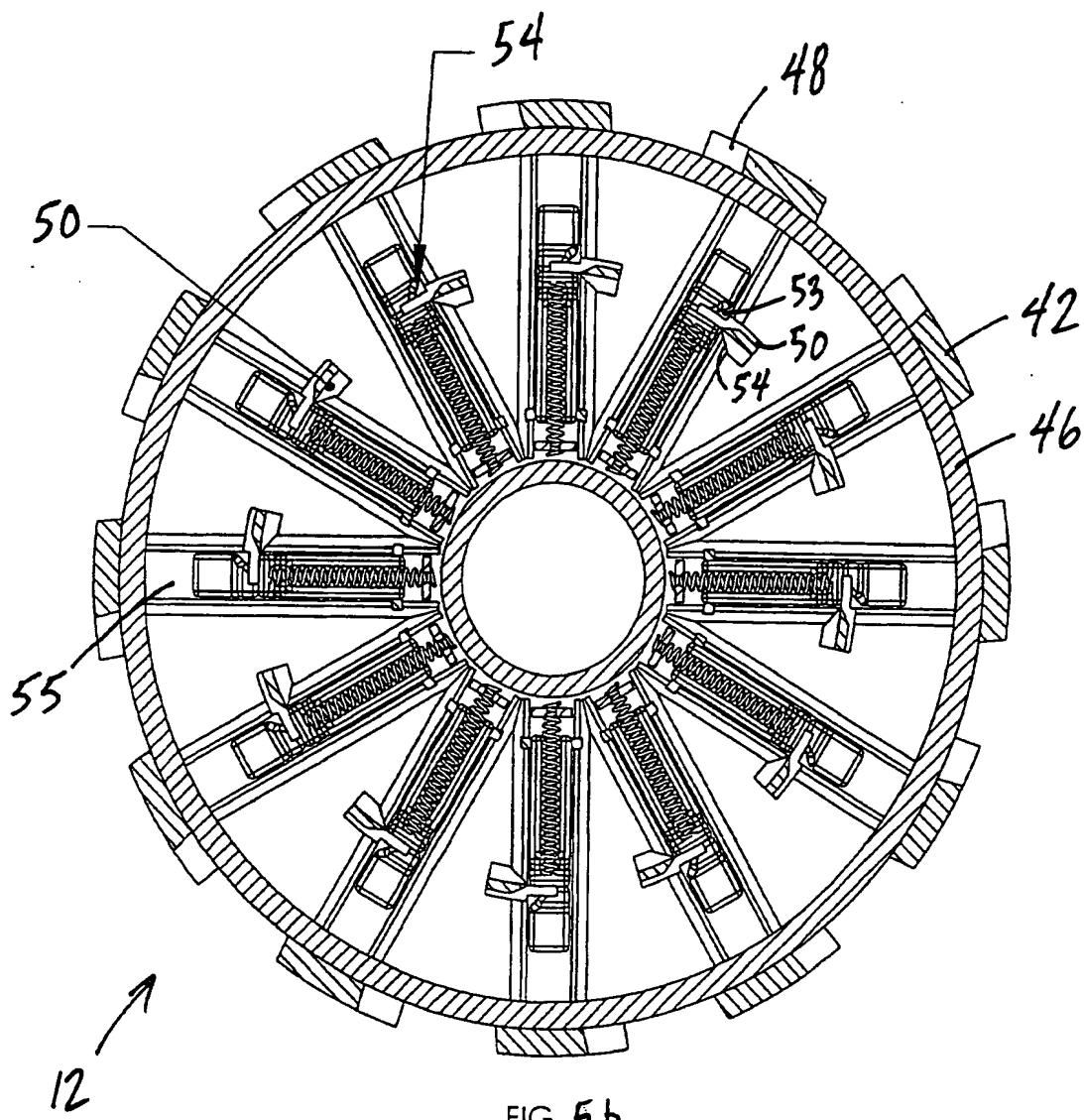


FIG. 5b

SECTION A-A

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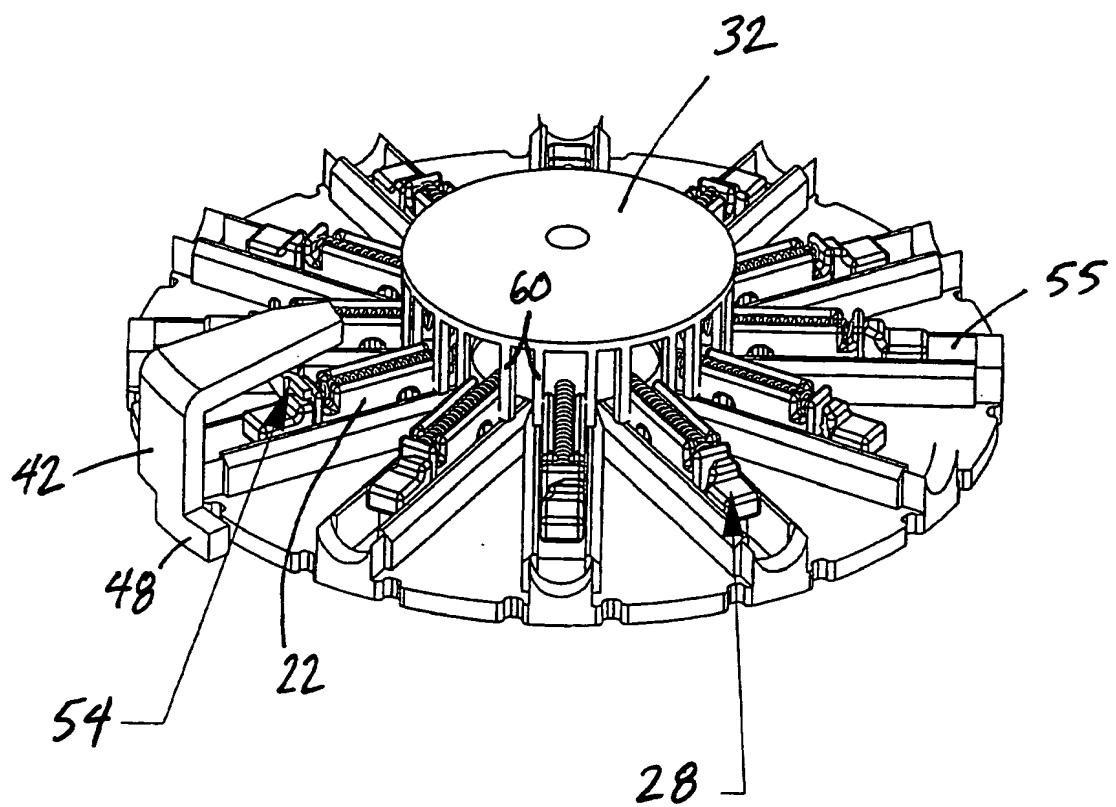


FIG. 6

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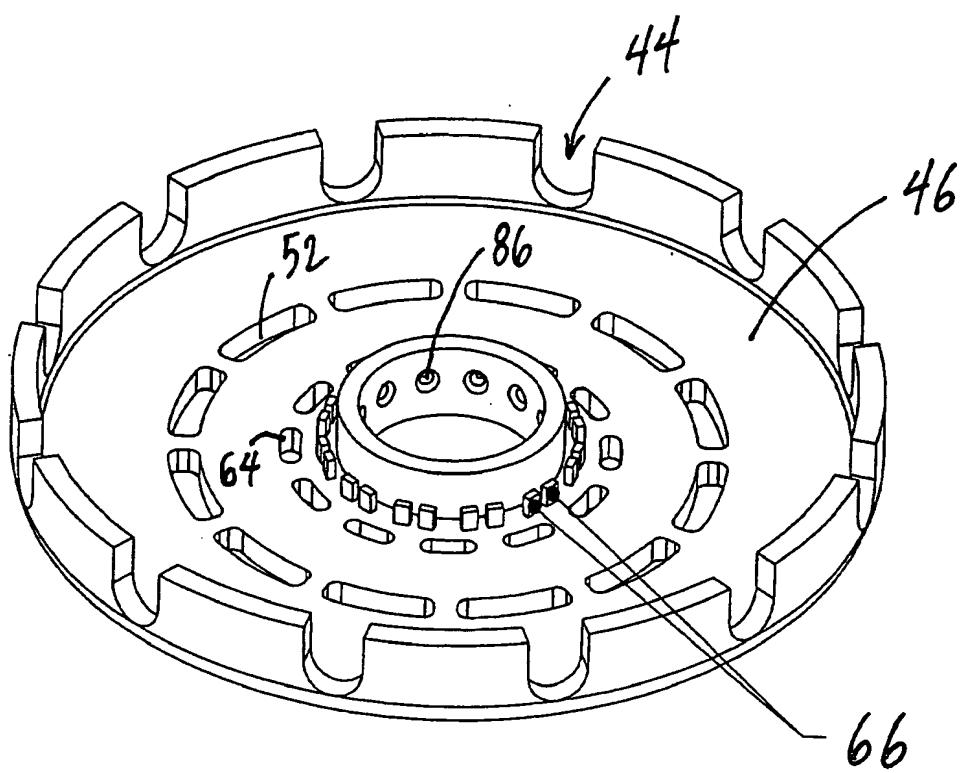
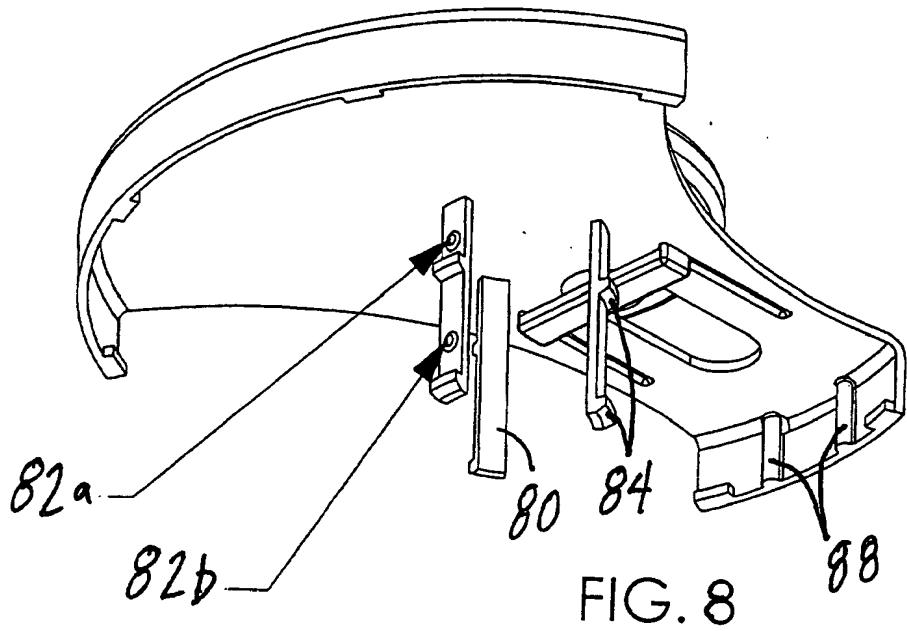


FIG. 7

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